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09/200,791	11/30/1998	THOMAS M. BEHR	018734/0161	9799

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EXAMINER
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 29

Application Number: 09/200,791
Filing Date: November 30, 1998
Appellant(s): BEHR ET AL.

Eve Frank
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/16/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

All claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Behr et al. "Reduction of the renal uptake of radiolabeled monoclonal antibody fragments by cationic amino acids and their derivatives" Cancer Research 55:3825-3834, Sept. 1, 1995.

5,380,513	Grey et al	1-1995
5,840,296	Raines et al	11-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-9, 11-21, 23-29, 31-37 are rejected under 35 U.S.C. 103. This rejection is set forth in prior Office Action, Paper No. 20 and follows.

Claims 1-21 and 23-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behr et al (Cancer Research 55:3825-3834, 1995), and further in view of Grey et al (U. S. Patent 5,380,513, issued 1/10/95, IDS #4) and Raines et al (U.S. Patent 5,840,296, filed 10/15/97).

Claims 1-4, 6, 8, 13-14, 18-19, 23-24, 26, 28, 33-34 have been described supra. Claims 5, 7, 9-12, 15-17, 25, 27, 29-32, and 35-37 recite wherein the conjugate is a therapeutic isotope, a protein conjugate comprising a cytotoxic agent, administering poly-D or poly-L-lysine wherein they have a molecular weight of 15-30 kD, wherein the compounds are administered by a bolus and orally administered,

Behr et al teach a method of reduction of renal uptake of a protein conjugate comprising a imaging or therapeutic moiety in a patient with addition of lysine and poly-lysine (15-30 kD) and the solutions were administered by iv or ip (see entire document). Behr et al does not teach a protein conjugate that is not an antibody conjugate or a conjugate comprising a ribonuclease. These deficiencies are made up for in the teachings of Grey et al and Raines et al.

Grey et al teach a method to reduce renal retention of protein conjugates with lysine (see abstract and column 3, lines 44 to column 4, lines 2). Grey et al teach the conjugates comprise imaging agents and therapeutic agents (see column 7), that comprise cytotoxins and the proteins comprise receptors and enzymes as well as other proteins (see columns 5-6) Grey et al also teach administration orally, iv, ip, or the like (column 6, lines 1-5).

Raines et al teach conjugates comprising ribonuclease which have been effective in tumor patients (see column 1) and the decrease in renal function of Onconase may be the consequence of an inability to effectively clear the Onconase protein from the kidneys (see column 2, lines 52-57). Onconase is a 104 amino acid protein (see column 2, lines 34-35) which is not greater than 60 kD.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a method for reducing kidney retention of protein conjugates in a patient with administration of compounds of lysine or poly-lysine in view of Behr et al, Grey et al, and Raines et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a method for reducing kidney retention of protein conjugates in a patient with administration of compounds of lysine or poly-lysine in view of Behr et al, Grey et al, and Raines et al because Behr et al teach that kidney retention was reduced in conjugates by addition of lysine and poly-lysine and that poly-lysine (15-30 kD) was more effective in reducing renal uptake (see page 3829). In addition, one of ordinary skill in the art would have been motivated to and had

a reasonable expectation of success to have produced a method for reducing kidney retention of protein conjugates in a patient with administration of compounds of lysine or poly-lysine in view of Behr et al, Grey et al, and Raines et al because Grey et al teach that protein conjugates comprising enzymes and added lysine can reduce renal uptake of the conjugates. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a method for reducing kidney retention of protein conjugates in a patient with administration of compounds of lysine or poly-lysine in view of Behr et al, Grey et al, and Raines et al because Raines et al teach "A cytotoxic ribonuclease that is readily cleared from the kidneys would be less likely to cause renal toxicity" (see column 2, lines 58-62). Thus it would have been obvious to one of ordinary skill in the art to produce a method of reducing renal uptake of protein conjugates that are not antibody conjugates in view of the teachings of Behr et al, Grey et al, and Raines et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

(11) Response to Argument

Appellants state that the present claims are patentable over the prior art because Behr et al and Raines et al are not prior art against the present application because the present application is entitled to a priority date of March 21, 1995 (see page 3-4 of Brief). In particular Appellants state that although the instant application is a CIP of 08/407,899, there are no claims pending that are directed to the specific embodiments

constituting the new matter that was added in the CIP. Appellants state that in particular column 1, lines 33-39 of the issued patent from the parent (US Patent 5,843,894) or page 2, lines 1-8 of the '899 application show support by description of a potential mechanism for renal uptake of peptides and small proteins is provided and one of ordinary skill in the art reading the specification as a whole would understand that Applicants possessed a generic scope extending the all such cytotoxic or imaging agents that are susceptible to renal uptake.

In response to these arguments, the stated location in the application, page 2, lines 1-8 or in the patent, column 1, lines 33-39 does not support the idea of excluding antibody or antibody fragment conjugates as recited in claims 1 and 18 in the method. The recited passage describes the mechanism of renal uptake in general for peptides and small proteins but does not support that the protein conjugate is not an antibody or antibody fragment conjugate. As stated the specification must be read as a whole and as such there is nothing in the disclosure to limit the conjugates as not antibodies or antibody conjugates. In fact in the summary of the invention as well as throughout the specification the only example or disclosure is for antibody fragment conjugates (see page 3, lines 1-4 of the '899 specification). Just because the background section of the application discusses a general method of renal uptake with peptides and small proteins does not support the idea of a protein conjugate that is not an antibody or antibody fragment.

Appellants state that an antibody is a protein and thus antibodies are a species of the protein genus and page 2, lines 1-8 of the '899 application describes a potential

mechanism for renal uptake of peptides and small proteins and this passage evidences that the specification is directed broadly to a method for reducing renal uptake of peptide and small protein conjugates and those methods are exemplified with antibody or antibody fragment conjugates (see page 5-6 of the Brief).

In response to these arguments, while it is true that antibodies are proteins, the cited passage cited (page 2, lines 1-8) as well as the whole specification does not support the claimed limitation of a method of reducing kidney retention of a protein conjugate wherein it is not an antibody or an antibody conjugate.

Appellants cite In re Johnson on page 5 and 6 of the Brief and summarize in a footnote in the Brief In re Johnson (see page 6) and state In re Johnson was directed to issues that pertain to 112 first and the court reversed the rejection, holding that the parent satisfied the 112 first paragraph for the "limited genus" claimed after exclusion from the original claims of two species specifically disclosed in the parent application. In response to this in In re Johnson fifty specific choices were mentioned for the compounds and in the instant application there is no mention of any other proteins except for antibodies and antibody conjugates.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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July 24, 2003

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